

**REMARKS**

The Examiner provides a number of restrictions, objections, and rejections. We list them here in the order in which they are addressed.

I. Applicants are asked to affirm their election of Group II, Claims 27-35, drawn to a device.

II. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include reference character 40 in Figure 1 without mentioning reference character 40 in the description.

III. Claims 27-35 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

IV. Claims 27-35 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Warman et al., U.S. Patent No. 6,091,988.

V. Claims 27-35 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Burnes et al., U.S. Patent Application Publication No. 2003/0204209.

**I. Applicants Affirm Their Election of Group II, Claims 27-35.**

As requested by the Examiner, Applicants hereby affirm the election with traverse to prosecute the invention of Group II, Claims 27-35.

**II. The Drawings Comply with 37 CFR 1.84(p)(5).**

As requested by the Examiner, Applicants have amended the specification to add the reference character (40) in the description in compliance with 37 CFR 1.121(b). See page 5 (above).

**III. Claims 27-35 Are Definite.**

The Examiner believes that Claim 27 does not provide sufficient antecedent basis for the term “said pacemaker element”. Without acquiescing to the Examiner’s argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 27 to recite “an implantable pacemaker element configured to initiate an anti-tachycardia pacing burst”. This amendment is made to further the Applicants’ business interests, better define one embodiment and expedite the prosecution of this application. The Applicants now believe that Claim 27 is allowable.

The Examiner rejected claims 32 and 33 for lack of sufficient antecedent basis for the claim limitation “said pacemaker element”. In light of the amendments to independent Claim 27, Applicants now believe that Claims 32 and 33, which depend from Claim 27, are allowable. Further, the Applicants have amended Claim 32 to correct a grammatical error, replacing the term “comprises” with “comprising”.

The Examiner rejected Claim 28, alleging that the phrase “a microprocessor” is inferentially included and it cannot be determined if the microprocessor is being positively recited or functionally recited. Without acquiescing to the Examiner’s argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 28 to recite that “said pacemaker element comprises a microprocessor configured to initiate said pacing burst.” This amendment is made to further the Applicant’s business interests, better define one embodiment and expedite the prosecution of this application. The Applicants now believe that Claim 28 is allowable.

The Examiner also rejected Claim 34, alleging that the phrase “capable of” is vague and indefinite. Without acquiescing to the Examiner’s argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar)

claims, Applicants have amended Claim 34 to recite “at least one defibrillation lead configured to convert an abnormal heart rhythm into normal sinus rhythm.” This amendment is made to further the Applicant’s business interests, better define one embodiment and expedite the prosecution of this application. The Applicants now believe that Claim 34 is allowable.

The Applicants point out that Claim 29 has been voluntarily amended to replace ‘defibrillator’ with ‘pacemaker’ in order to maintain proper antecedent basis.

In light of the amendments described above, Applicants respectfully request that the Examiner withdraw the present rejection.

#### **IV. Claims 27-35 Are Not Anticipated By Warman.**

As the Examiner is well aware, a single reference must disclose each limitation of a claim in order for that reference to anticipate the claim. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed Cir. 1984). This criterion is not met with the Warman reference.

The Examiner states that:

Warman et al. disclose...a plurality of atrial and ventricular sensing leads (e.g., FIGS. 1-2); configure to detect an earliest arriving electrical signal (e.g., col. 8, lines 8-12...; additionally, both leads will “detect” the earliest arriving electrical signal when in detection configuration); generates anti-tachycardia pacing burst (claim 29) (e.g., column 4, lines 64-66).

*Office Action* pg 4 ¶9. The Applicants disagree. The Examiner is requested to note that the sensing leads of Claim 27 detect an earliest arriving signal following an anti-tachycardia pacing burst. Unlike the sensing leads of the present invention, the sensing leads disclosed in Warman et al. merely detect an electrical signal following delivery of a cardioversion or defibrillation pulse; not anti-tachycardial pacing. *Warman*, col 7 ln 58-col 8 ln 12. While Applicants disagree with the Examiner’s assertion that the sensing leads of the present invention and the sensing leads disclosed by Warman will both “detect” the earliest arriving electrical signal, this point is irrelevant in light of the fact that the electrical signal disclosed by Warman and the electrical signal of the present invention are dissimilar.

Applicants point to the Examiner's assertion that *col. 4, lines 64-66* of Warman discloses anti-tachycardia pacing burst as further proof that the Examiner erroneously considers the terms "defibrillation" and "anti-tachycardia pacing" as being interchangeable. The term "anti-tachycardia pacing" does not appear in *col. 4, lines 64-66*. To further support this distinction, Applicants respectfully direct the Examiner's attention to *Warman col. 5, lines 14-16*, "... cardioverters and defibrillators which do not provide anti-tachycardia pacing therapies..." and *Warman col. 8, lines 63-66*, "If repeated attempts at anti-tachycardia pacing therapies fail, a higher level cardioversion pulse may be selected thereafter" as evidence that anti-tachycardia pacing and defibrillation are not synonymous.

Further, the Examiner is respectfully requested to reconsider the argument that:

With respect to claim 34, converting an abnormal beat rhythm into normal sinus rhythm is inherently realized when anti-tachycardia pacing is administered because the result of said pacing makes the heart beat normal which is what normal sinus rhythm is...

*Office Action pg 4 ¶10.* The Examiner is requested to take note that an abnormal heart rhythm is not inherently realized when anti-tachycardia pacing is administered. *See, Declaration of Dr. Samir Saba ¶ 4.* In fact, defibrillation is administered in situations where anti-tachycardia pacing has failed to convert an abnormal heart rhythm into a normal sinus rhythm. *See Warman col. 8, lines 58-64.*

Based on the preceding arguments, the Applicants contend that Warman does not anticipate Claims 27-35. Therefore, Applicants respectfully request the Examiner withdraw the present rejection. Applicants further contend that since independent Claim 27 is patentable, all dependent Claims are patentable as well.

#### **V. Claims 27-35 Are Not Anticipated By Burnes.**

As the Examiner is well aware, a single reference must disclose each limitation of a claim in order for that reference to anticipate the claim. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed Cir. 1984). This criterion is not met with the Burnes reference.

The Examiner states that:

Burnes et al. disclose an implantable pacemaker, an implantable defibrillator element and a plurality of atrial and ventricular sensing leads....; initiate an anti-tachycardia pacing burst and detect an earliest arriving electrical signal (e.g., FIGS. 3-5); defibrillator generates anti-tachycardia pacing burst....

*Office Action* pg 5 ¶13. The Applicants disagree. The Examiner is requested to note that in Figures 3-5 of Burnes, following delivery of programmed anti-tachycardia pacing therapies (420), the next step is to “detect termination” (425) of the tachycardia, and not to “detect an earliest arriving electrical signal” as indicated by the Examiner. Applicants respectfully contend that the “detect termination” step disclosed by Burnes is not disclosed as relying upon the discrimination or identification of an earliest arriving electrical signal.

Further, Applicants respectfully contend that of the four citations provided by the Examiner as evidence that Burnes discloses a defibrillator that generates an anti-tachycardia pacing burst (*Office Action*, pg 5 ¶3), none of them actually disclose such an element. Element 230, mentioned only in paragraph [0037] and Figure 2, merely discloses “cardioversion and defibrillation control circuitry”. Paragraph [0008], lines 1-4 does not disclose a defibrillator that delivers anti-tachycardia pacing, but merely that “...an implantable medical device for delivering anti-tachyarrhythmia and defibrillation therapies to the heart...in the form of pacing or shocking pulses...”. Paragraph [0023], lines 3-8 discloses “electrical shocks for cardioversion and defibrillation therapies”, but makes no mention of “pacing” or “anti-tachycardia”. Finally, paragraph [0037] discloses, “delivering anti-tachycardia pacing therapy” in response to the detection of tachycardia, but does not state that the defibrillator is responsible for delivering this treatment. In fact, this paragraph actually discloses, “That in the event higher voltage cardioversion or defibrillation pulses are required, microprocessor 224 activates the cardioversion and defibrillation control circuitry...”, thus teaching away from a defibrillator that generates anti-tachycardia pacing bursts.

Further, the Examiner is respectfully requested to reconsider the argument that:

Additionally, normal sinus rhythm is inherently realized when anti-tachycardia pacing is administered because the result of said pacing makes the heart beat normal, which is what normal sinus rhythm is...

*Office Action pg 5 ¶13.* The Examiner is requested to take note that an abnormal heart rhythm is not inherently realized when anti-tachycardia pacing is administered, this is in fact the very reason that defibrillation is administered in the event that anti-tachycardia pacing fails to convert an abnormal heart rhythm into a normal sinus rhythm. *See Warman col. 8, lines 58-64; and The Declaration of Dr. Samir Saba ¶ 4.*

Based on the preceding arguments, the Applicants contend that Burnes does not anticipate Claims 27-35. Applicants therefore respectfully request the Examiner withdraw the present rejection.

## **CONCLUSION**

Based on the arguments provided above, Applicants believe that Claims 27-35 are in condition for allowance. Should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned at 617-984-0616.

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